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| 10/597,296 | 10/07/2008 | **Robert James Nash** | 3073.075 | 8910 |

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| EXAMINER | |
|---|---|
| THOMAS, TIMOTHY P | |
| **ART UNIT** | **PAPER NUMBER** |
| 1628 | |
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| 04/06/2011 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/597,296 | NASH ET AL. | |
| | Examiner | Art Unit | |
| | TIMOTHY THOMAS | 1628 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *18 January 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *43-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Arguments*

1. Applicants' arguments, filed 1/18/2011, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

2. Applicant's arguments with respect to the rejection under 35 USC 112, 2nd paragraph have been fully considered but they are not persuasive:

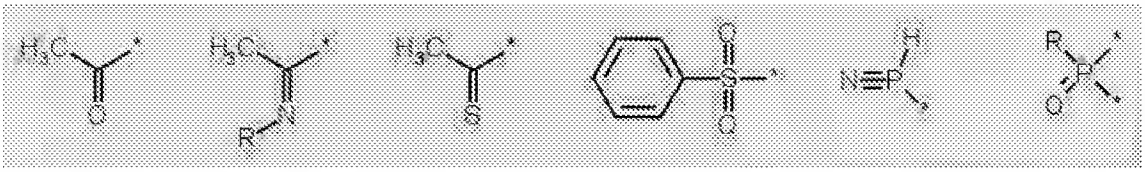
Claims 43-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The additional comments are necessitated by the claim amendment.

With respect to claims 43-60, the claim amendment to modify “derivatives” to "acyl derivatives" still does not make clear which compounds are within the metes and bounds and which are excluded by the amended language.

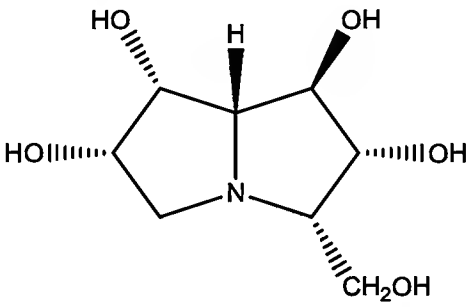
IUPAC Gold Book defines acyl groups as follows (see IUPAC GoldBook ; “acyl groups”; http://goldbook.iupac.org/A00123.html; accessed online, 4/4/2011):

> **acyl groups**
> Groups formed by removing one or more hydroxy groups from oxoacids that have the general structure $R_kE(=O)_l(OH)_m$ ($l \neq 0$), and replacement analogues of such acyl groups. In organic chemistry an unspecified acyl group is commonly a carboxylic acyl group. E.g.



***Source:***
PAC, 1995, *67*, 1307 *(Glossary of class names of organic compounds and reactivity intermediates based on structure (IUPAC Recommendations 1995))* on page 1311

This definition of an acyl group indicates some group formed by removal of the hydroxy from an oxoacid. The instant elected compound, 3,7-diepi-casuarine, has the structure




;

This compound does not have any such oxoacid group present, from which a hydroxy moiety can be removed to form an acyl group of the type discussed in the Gold Book. Nor does it follow how the elected compound would be derivatized to contain any of the acyl groups exemplified by IUPAC. Even if the language "acyl derivative" were construed to mean a compound formed from some claimed compound that contains an acyl group (which is not clear in view of the specification and instant claims), it still would remain indefinite as to what compounds would be embraced by the recited “acyl derivative” limitation, based on the IUPAC definition. One of ordinary skill in the art would not be able to immediately envisage which compounds are embraced by this

limitation. For the purpose of prior art determination the phrase “acyl derivative” is construed to mean any “derivative”.

With respect to claims 61-62, the Th-1 activating alkaloid basis is withdrawn, based on the structure introduced into the claims; however, the claim amendment introduces "acyl derivatives", which still does not make clear which compounds are within the metes and bounds and which are excluded by the amended language.

Claims 43, 47, 48 and amended language of claims 61-62 still contain “e.g.” or “for example”; this language renders the claims indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Applicant argues that the amendment to "acyl derivatives" is believed to clarify the scope of the phrase. This language is still indefinite with respect to which compounds are embraced by and which are outside of the scope of this language, as discussed above.

Applicant argues that the “for example (e.g.)” language has been resolved. This language is still present in the designated claims, for which this rejection basis is maintained.

3. Applicant's arguments with respect to the obviousness rejection of claims 43-56 and 59-62 have been fully considered but they are not persuasive:

Claims 43-56 and 59-62 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Watson et al. (“Polyhydroxylated alkaloids -- natural occurrence and therapeutic applications"; 2001; Phytochemistry; 56: 265-295: IDS reference CD); in

view of Clements et al. ("The global impact of vaccines containing aluminium adjuvants"; 2002; Vaccine 20: S24-S33).

The rejection is maintained for the reasons of record.

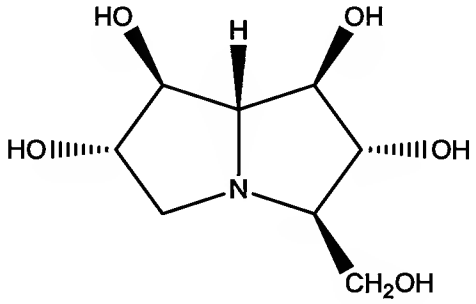
Applicant argues that previous case law In re Grabiak and In re Grunwell have held that significant structural differences, such as those present in the case, preclude a finding of obviousness based on structural similarity; that according the decision in Grabiak, generalization should be avoided insofar as specific chemical structures are alleged to be *prima facie* obvious from one another; that there must be adequate support in the prior art for any differences in structure between the prior art structures and the structures at issue to support a *prima facie* case of obviousness; that because the prior art did not provide any indication that substituting a sulfur atom for an oxygen atom would provide desired function to the resulting molecule, the Court held a finding of obviousness unsupportable; that the court found that differences existing between the ring structure of the prior art compounds and the compounds at issue was highly significant in finding a lack of structural similarity.

The instant facts differ from *Grabiak*. *Grabiak* was based on obviousness of substitution of S for O based on unrelated heterocyclic rings, based on unrelated molecules for which this substitution was taught. The Court stated (p. 872):

> The Bollinger teaching of various heterocyclic rings containing either two sulfur atoms or one oxygen and one sulfur atom, rings which are unlike any part of the Howe molecule, does not suggest the interchangeability of sulfur for oxygen in the ester moiety of the Howe molecule.

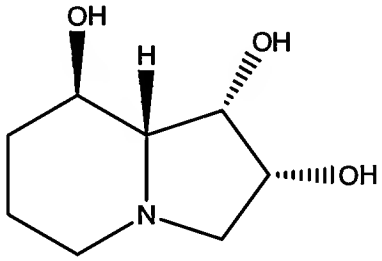
The instant case for obviousness is based on related structural features in common, in contrast to the comparison made to Bollinger. The record indicates, in part:

Watson teaches a series of polyhydroxylated alkaloids, which include the compounds



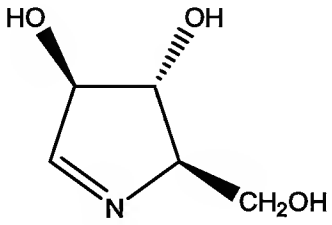

Casuarine

(p. 274, Figure 5, 2nd row);




Swainsonine

(p. 275, Figure 6, 1st row); and




Nectrisine

(p. 273, Figure 2, 1st row). ...

> This article establishes that both swainsonine and nectrisine have the properties of immune stimulants. Considering the structures of these compounds and the related alkaloid, casuarine indicates that nectrisine has the same 5-membered pyrole moiety including the OH and CH2OH substituents, in the same 3-D arrangement as casuarine, would have lead to an expectation that casuarine would have activity as an immune stimulant. Comparison of swainsonine with nectrisine, shows the common features of the molecules are the 5-membered pyrrole moiety, and three hydroxy groups, with similar distance between the hydroxyl groups. These common molecular features are also present in causuarine. Therefore, one of ordinary skill in the art would have a reasonable expectation that the alkaloid casuarine would also function as an immune stimulant, similar to swainsonine and nectrisine.

The point is that both molecules, nectrisine and swainsonine, each contain substantial portions of the casuarine molecule. Since each independently was recognized to have immune stimulant activity, one of ordinary skill in the art would have had a reasonable expectation that casuarine would also have been active as an immune stimulant.

Applicant argues that in *Grunwell*, the CCPA held that certain prior art compounds were not similar enough to the compound at issue to support a finding of obviousness because one compound was an alcohol and the other its ether; that the decision was based on finding that the prior art references did not show any support for the substitution and thus could not support a prima facie case of obviousness; that the court did hold that one compound at issue was structurally similar enough to a prior art

compound to be considered structurally similar, where the compounds differed only in the addition of a methyl group to the compound at issue; but that such a substitution is not per se obvious and there were several factors in the prior art reference that suggested such a substitution would be acceptable, including an identical base ring structure and analogous physiological and psychological responses by both compounds. The instant case is not based on substitution of an alcohol for an ether; it is based on recognition that a molecule with similar portions of the external substituent, and substantial portions of the ring structures in common have recognized properties as immune stimulants; the casuarine molecule contains most of the parts of the two other molecules; thus it would have been reasonable to expect immune stimulant activity from casuarine.

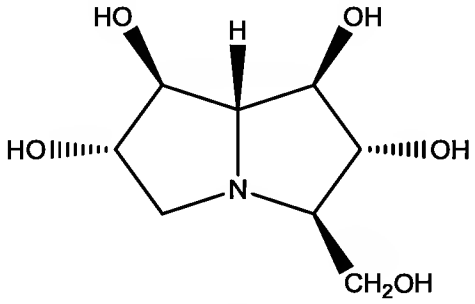
Applicant argues there is a low amount of structural similarity between casuarine an either swainsonine or nectrisine, not enough to lead one of skill in the art the casuarine or other compounds of the present invention would likely have immune stimulant properties; that a critical difference between casuarine and either swainsonine or nectrisine is that the core ring structures are very different; specifically, casuarine contains a bicyclic compound having two five-membered rings which swainsone contains a bicyclic ring structure having on six-membered ring and one five-membered ring; that nectisine is even further removed from casuarine, being only monocyclic. The monocyclic portion of nectrisine is identical to the right side five-membered ring of casuarine, including all substituents in the exact same special orientation. Thus, it would have been reasonable that if nectrisine was active as an immune stimulant,

presumably from the portion of the molecule with substituents being oriented toward some biological target, the identical portion of the casuarine molecule would approach the same target in the same geometry, having a similar activity. Similarly, the upper half of the swainsonine have the same substituents, with nearly the same core structure, i.e., a similar size of the bi-ring structure. Approach to a biological target by swainsonine from this portion of the molecule would be expected to have a similar result if casuarine approached the same target. Considering that both nectrisine and swainsonine have immune stimulant activity, and together represent nearly all of the casuarine molecule, one of skill in the art would have had a reasonable expectation that casuarine would have also had immune stimulant properties.

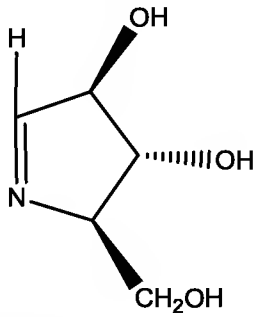
Applicant argues that the substituents attached to the core ring structures are significantly different; that casuarine has four hydroxyl groups and a hydroxymethyl group attached to the bicyclic ring structure, while swainsonine has only three hydroxyl groups attached to this ring structure and no hydroxymethyl group; that nectisine is even further removed in light of its monocyclic structure and it includes only two hydroxyl groups and a hydroxymethyl group. This is not persuasive; nectirsine has the identical structure as the right side ring structure, including each substituent at the identical stereochemical geometry. It is true that there is an additional ring with two additional hydroxy groups on the casuarine molecule; however, one of ordinary skill in the art would expect that the fitting of nectrisine molecule into a location at some biological target would reasonably be approximated by casuarine; i.e., leading to similar biological activity as an immune stimulant. Similarly, a substantial portion of the

swainsonine molecule substiuents would have been shared with casuarine, leading to an expectation that casuarine would approach the same target as swainsonine, and result in similar immune stimulation activity. When the two compounds are taken together, nectrisine and swainsonine have all of the same substituents as casuarine, with the exception of the left-side hydroxy group. Since both molecules are immune stimulants, there would have been a reasonable expectation for casuarine to also have the property of immune stimulant.

Applicant argues that there are significant differences between casuarine and both swainsonine and nectrisine with regard to the cis-trans orientation of the substiuent groups. This is not accurate with respect to the nectrisine casuarine comparison. All analougous substituents have the same orientation, which is seen with this comparison:

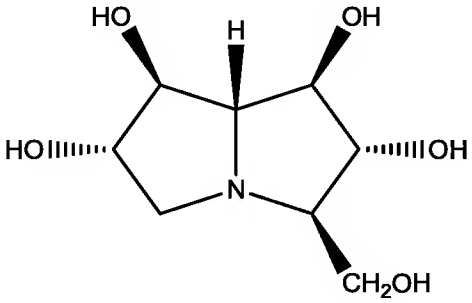



Casuarine

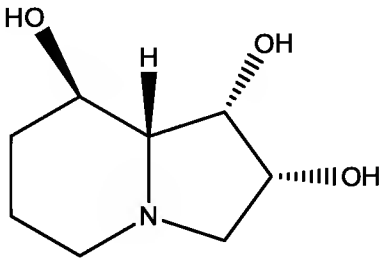



Nectrisine

There is a difference with the upper right hydroxy group of swainsonine v. casuarine:




Casuarine




Swainsonine

However, considering nectisine has the alternate orientation, would have lead to an expectation that casuarine would also have been active in immune stimulation.

Applicant further argues the specificity of the immune response type from a type 2 to a type 1 is not taught; that the specificity of the immune response elicited by the compounds of the present invention is one of the novel features of the invention and cannot be ignored when making an obviousness analysis; because nothing in Watson even mentions the different classes of immune response, applicant asserts that one of skill in the art would have had no indication that casuarine or any other compound of the present invention would have the effect of stimulating a type-1 response or shifting an immune response from a type-2 response to a type-1 response.

As is present on the record: It is noted that the language of claim 43, 61 and 62, "polarizing an immune response to an antigen" appears in the preamble and is not given patentable weight. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

The language "in an amount effective to polarize an immune response to the antigen(s) from type 2 towards type 1" is a limitation regarding the "amount" of compound administered. Absent evidence to the contrary, the administration of the

amount of casuarine effective for the obvious use of immune stimulation would have also satisfied this claim limitation.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Applicant argues that claim 43 limits the scope of permissible derivatives, thus excluding both swainsonine and nectrisine from their scope. This position is noted. However, as discussed above, it is not possible to determine which compounds are within the scope of acyl derivatives; thus, it is assumed the claim encompasses all “derivatives”, including swainsonine and nectrisine. However, even if swainsonine and nectrisine are excluded from the claim language, applicant’s argument does meet the burden of establishing that casuarine would not possess the recited property.

4. Applicant's arguments with respect to the obviousness rejection of claims 43-44, 49, 51, 53, 55 and 59-62 have been fully considered but they are not persuasive:

Claims 43-44, 49, 51, 53, 55 and 59-62 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Watson et al. (“Polyhydroxylated alkaloids -- natural occurrence and therapeutic applications"; 2001; Phytochemistry; 56: 265-295: IDS reference CD); in view of Clements et al. (“The global impact of vaccines containing aluminium adjuvants”; 2002; Vaccine 20: S24-S33) as applied to claims 43-56 and 59-

62 above, and further in view of Bell et al. ("Synthesis of Casuarines [Pentahydroxylated Pyrrolizidines] by Sodium Hydrogen Telluride-Induced Cyclisations of Azidodimesylates"; 1997; Tetrahedron Letters; 38(33): 5869-5872: IDS reference CA).

The rejection is maintained for the reasons of record.

Applicant argues the same arguments that were addressed in the rejection discussed above. Each argument has been addressed above.

5. Applicant's arguments with respect to the obviousness rejection of claims 57-58 have been fully considered but they are not persuasive:

Claims 57-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watson et al. ("Polyhydroxylated alkaloids -- natural occurrence and therapeutic applications"; 2001; Phytochemistry; 56: 265-295: IDS reference CD); in view of Clements et al. ("The global impact of vaccines containing aluminium adjuvants"; 2002; Vaccine 20: S24-S33) as applied to claims 43-56 and 59-62 above, and further in view of Slovin et al. ("Peptide and carbohydrate vaccines in relapsed prostate cancer: immunogenicity of synthetic vaccines in man—clinical trials at Memorial Sloan-Kettering Cancer Center"; 1999; Semin. Oncol; 26(4): 448-54; PubMed abstract; PMID: 10482187).

The rejection is maintained for the reasons of record.

Applicant argues the same arguments that were addressed in the rejection discussed above. Each argument has been addressed above.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 43-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is necessitated by the claim amendment adding the limitation "acyl derivative".

The amended claims recite "acyl derivatives" of the recited compounds, in claims 43, 59, 60, 61 and 62, which include "acyl derivatives" of the elected compound, 3,7-diepi-casuarine. A review of the specification did not identify disclosure of acyl derivatives of the claimed compounds, or acyl derivatives of the elected compound, to demonstrate applicant was in possession at the time of filing of the generic phrase or to place the public in possession of this generic group of compounds.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention,

> with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

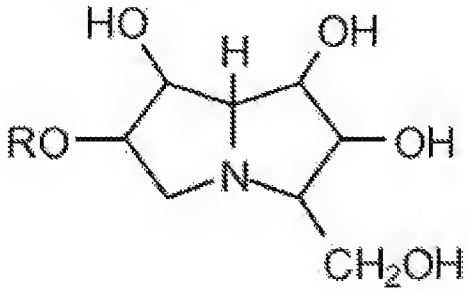
> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*,

the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

In the instant case, the claims are drawn to a method of polarizing an immune response to an antigen in a subject, comprising administering to the subject a vaccine comprising one or more antigen(s) and an adjuvant composition comprising a TH1-activating alkaloid in an amount effective to polarize an immune response to the antigen(s) from type 2 towards type 1, wherein the alkaloid has the formula:

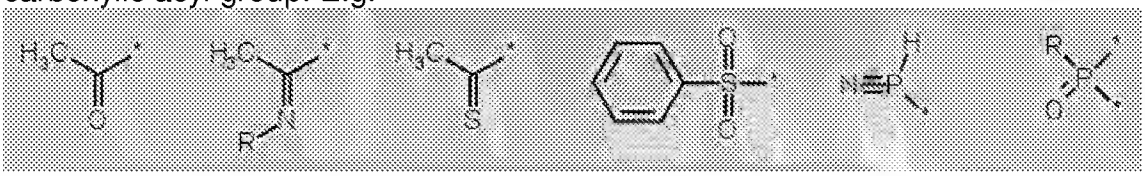


wherein R is selected from the group comprising hydrogen, straight or branched, unsubstituted or substituted, saturated or unsaturated acyl, alkyl (e.g., cycloalkyl), alkenyl, alkynyl and aryl groups, or a pharmaceutically acceptable salt or acyl derivative thereof.

*(1) Level of skill and knowledge in the art:*

The level of skill and knowledge in the art are high.

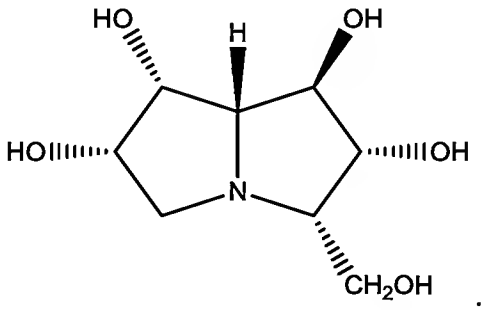
As discussed above, IUPAC Gold Book defines acyl groups as follows (see IUPAC GoldBook ; "acyl groups"; http://goldbook.iupac.org/A00123.html; accessed online, 4/4/2011):

> **acyl groups**
> Groups formed by removing one or more hydroxy groups from oxoacids that have the general structure $R_kE(=O)_l(OH)_m$ ($l \neq 0$), and replacement analogues of such acyl groups. In organic chemistry an unspecified acyl group is commonly a carboxylic acyl group. E.g.
>
> 
>
> ***Source:***
> PAC, 1995, *67*, 1307 *(Glossary of class names of organic compounds and reactivity intermediates based on structure (IUPAC Recommendations 1995))* on page 1311

This definition of an acyl group indicates some group formed by removal of the hydroxy from an oxoacid.

*(2) Partial structure:*

The instant elected compound, 3,7-diepi-casuarine, is disclosed; this compound has the structure




This compound does not have any oxoacid group present, from which a hydroxy moiety can be removed to form an acyl group of the type discussed in the Gold Book. Nor does it follow how the elected compound would be derivatized to contain any of the acyl groups exemplified by IUPAC. Even if the language "acyl derivative" were construed to mean a compound formed from some claimed compound that contains an acyl group (which is not clear in view of the specification and instant claims), it is still unclear which portion of the molecule is required to satisfy the recited “acyl derivative” limitation, based on the IUPAC definition.

It is noted that no identified examples of acyl derivatives of this compound could be identified in the specification, nor was disclosure found to identify what is even meant by "acyl derivatives" of the claimed compounds, or what portion of the molecule would be retained in any derivatives of the elected or other claimed compounds.

*(3) Physical and/or chemical properties and (4) Functional characteristics:*

The compounds are disclosed and claimed to be Th1 activating alkaloids, alleged and claimed to be effective to polarize an immune response to an antigen from type 2 towards type 1.

*(5) Method of making the claimed invention:*

No method of making any acyl derivative of any claimed compound was identified in the specification, including for any acyl derivative of the elected compound.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 43-62 is/are broad and generic, with respect to all possible compounds encompassed by the claims. The possible structural variations are limitless to any compound that might be considered an acyl derivative of the elected or claimed compounds. Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond those compounds specifically disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. While having written description of the elected compound and compounds identified in the specification tables and/or examples, the specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention.

See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

***Conclusion***

8. No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY THOMAS whose telephone number is (571)272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy P Thomas/
Primary Examiner, Art Unit 1628